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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/883,033 | 06/15/2001 | Jean-Louis Imbach | 06171..105026(NOV 1005) | 4301 |

7590 12/31/2002

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| EXAMINER | |
|---|---|
| OWENS JR, HOWARD V | |
| **ART UNIT** | **PAPER NUMBER** |
| 1623 | |

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application N . | Applicant(s) | |
|---|---|---|---|
| | 09/883,033 | IMBACH ET AL. | |
| | Examin r | Art Unit | |
| | Howard V Owens | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 August 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *156,163 and 175-241* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *156,163 and 175-241* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

***Election/Restrictions***

Applicant submitted a response on 8/27/2002 to the restriction requirement mailed 7/16/2002. Applicant did not elect a group in the response to the restriction requirement; however, applicant canceled all claims that were not related to compositions containing a 3' amino acid substituted pyrimidine nucleoside. Given the cancellation of claims 1-155; 157-162 and 164-174 as well as the addition of new claims 175-241, the following restriction/election is required.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 156, 163, 175-209 drawn to 3' amino acid substituted pyrimidine compounds/compositions, classified in class 536, subclass 28.4.

   II. Claims 210-231 drawn to 3' amino acid substituted pyrimidine compositions in combination with one or more anti-hepatitis B virus agents, classified in class 514, subclass 49, 894.

   III. Claims 232-245 drawn to 3' amino acid substituted pyrimidine compositions in various delivery forms, classified in class 514, subclass 49+ and class 424, subclass 464.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as two distinct pharmaceutical compositions wherein each can be used for the treatment of hepatitis B; however the invention of Group II requires a more burdensome search by the addition of one or more anti-hepatitis B virus agents.

3. Invention III is related to inventions I and II as the various delivery form(s) of the compositions set forth in Groups II and III. Invention III will be examined upon election of either Group I or II.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 - ribavarin, class 514 , subclass 252.1+.

Species 2- cis-2-hydroxymethyl-5-(5-fluorcytosin-1-yl)-1,3 (3TC) class 514, subclass 274.

Species 3- DXG, DAPD, ACP, class 536, subclass 27.21 .

Species 4- L-FDDC, class 544, subclass 317.

Species 5- interferon, class 530 , subclass 300+.

Species 6 – entecivir, penciclovir, famciclovir, ganciclovir, lobucavir, class 546, subclass 276.

Species 7 – BMS-200475, class 514, subclass 45+.

Species 8 – bis pom PMEA, class 514 , subclass 344.

Species 9 – ribavarin, class 514 , subclass 252.1+.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 231 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.